IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. TIMOTHY D. WARREN, D.C. and TITAN MEDICAL COMPLIANCE, LLC, Defendants.	CIVIL ACTION NO.

COMPLAINT

The United States of America brings this action under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), against defendant Timothy D. Warren, D.C. ("Warren") and his wholly owned company Titan Medical Compliance ("Titan") (collectively "Defendants") for falsely promoting auricular electro-acupuncture devices, specifically the P-Stim, ANSiStim, and Stivax devices, as reimbursable by Medicare and as approved by the Food and Drug Administration ("FDA"). The P-Stim, ANSiStim, and Stivax devices can be applied in a few minutes in an office setting without anesthesia by someone with minimal training. The FDA has never approved these devices for any indication and Medicare has never approved reimbursement for them. But distributors of the P-Stim, ANSiStim and Stivax devices paid Warren – a self-proclaimed expert in medical coding and reimbursement – tens of thousands of dollars to convince medical providers that they could reap vast profits by billing Medicare for these devices. Warren knew Medicare did not reimburse for acupuncture, but nevertheless took his cut and instructed providers to bill Medicare using high reimbursement codes intended for complex

neuro-stimulators that specialized surgeons implanted into patients under anesthesia in a surgical setting. Many providers followed his advice. Warren's false promotion of the P-Stim, ANSiStim, and Stivax devices caused Medicare to pay tens of millions of dollars in false claims, for which the government now seeks damages and penalties under the FCA. Exhibit A.[1]

I. THE PARTIES

1. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS"), the United States Department of Defense ("DoD"), and Defense Health Agency ("DHA") (collectively, the "United States").

2. Defendant Timothy D. Warren is a chiropractor who owns and operates defendant Titan Medical Compliance LLC ("Titan"), along with Titan Medical Center LLC and Titan Medical Billing LLC. All have a principal place of business at 1415 W. 31st Street South, Wichita, Kansas, 67217.

I. JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345. This civil action arises under the laws of the United States, and this civil action is brought by the United States as a plaintiff pursuant to the FCA.

4. The Court may exercise personal jurisdiction over defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because

[1] Exhibit A shows 100 representative examples of the thousands of claims submitted to and paid by Medicare.

defendants can be found in and/or have transacted business within the Eastern District of Pennsylvania.

5. Venue is proper in the Eastern District of Pennsylvania under 31 U.S.C. § 3732(a), because Warren's actions caused medical providers located in the Eastern District of Pennsylvania to submit false claims to Medicare in violation of 31 U.S.C. § 3730.

II. LEGAL AND REGULATORY FRAMEWORK

A. The False Claims Act

6. The FCA provides, in pertinent part, that any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent; [or]

(C) conspires to commit a violation of subparagraph (A) [or] (B) . . .

(D) is liable to the United States Government [for statutory damages and such penalties as are allowed by law]." 31 U.S.C. §§ 3729(a)(1)-(3) (2006), as amended by 31 U.S.C. § 3729(a)(1)(A)-(C) (2010).

7. The FCA further provides that "knowing" and "knowingly"

(A) means that a person, with respect to information —

i. has actual knowledge of the information;

ii. acts in deliberate ignorance of the truth or falsity of the information; or

iii. acts in reckless disregard of the truth or falsity of the information; and

(B) requires no specific intent to defraud.

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

8. The FCA, 31 U.S.C. § 3729(a)(1), provides that any person who violates the FCA is liable to the United States Government for three times the amount of damages which the

Government sustains because of the act of that person, plus a civil penalty of not less than $5,000 and not more than $10,000 for each claim, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.5 (setting forth the current penalties level of not less than $11,665 and not more than $23,331 for each violation of the FCA).

B. The Medicare Program

9. In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq*., to provide health insurance coverage for people 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

10. The Medicare Program is administered by CMS, which is part of HHS. At all times relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

11. The Medicare Program provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or injury or to improve a malformed body part. Payment will be provided if medical necessity can be substantiated. Section 1862(a)(1) of the Social Security Act; CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Ch. 16, sec. 20.

12. The Medicare Program consists of four parts: A, B, C, and D. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

13. Medicare Part B covers medically necessary services, including provider visits, diagnostic tools that meet accepted standards for medical practice, procedures, medical supplies, and durable medical equipment.

14. Enrolled providers may submit bills to the Medicare Program for services rendered to the patients.

15. The Medicare Program only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

16. To obtain reimbursement from the Medicare Program, providers submit a claim form, CMS Form 1500 and/or its electronic equivalent, known as the 837P form.

17. Among the information the provider includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Ch. 23, § 20.7 *et seq*.

18. CPT codes are widely used in the United States as the way medical providers seek reimbursement for professional services from healthcare payors, including Medicare, other federal healthcare programs, and many private insurers.

19. HCPCS Level II codes are widely used in the United States as the way medical providers seek reimbursement for medical products, supplies, and equipment from healthcare payors, including Medicare, other federal healthcare programs, and many private insurers.

20. The American Medical Association ("AMA") defines the CPT and HCPCS codes in manuals published annually.

21. At all relevant times, the AMA coding manual has stated these instructions for selecting appropriate codes: "Select the name of the procedure or service that accurately

identifies the service performed. Do not select a CPT code that merely approximates the service provided."

22. Providing accurate CPT and HCPCS codes on claims submission forms is material to and a condition of payment for the Medicare Program. *See, e.g.,* Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

23. The Medicare Program routinely denies payment to providers who bill for codes when the criteria for those codes is not actually met, including when the services are not performed.

C. TRICARE

24. TRICARE is a federal healthcare program that is administered by the Defense Health Agency ("DHA"), a component of DoD. TRICARE provides health care insurance for active-duty military personnel, military retirees, and military dependents.

25. TRICARE contracts with one of two contractors, including Humana Government Business, Inc., d/b/a/ Humana Military, to administer the TRICARE program, including the processing and payment of claims for reimbursement of physician and mid-level providers' services from TRICARE.

26. TRICARE requires that appropriate medical records be maintained to substantiate that billed services were rendered. 32 C.F.R. § 199.7(b)(3). Failure to document the care billed will result in denial of payment by TRICARE. *Id.*; TRICARE Policy Manual 6010.60-M, Ch. 1, § 5.1, ¶ 3.2.

27. TRICARE has specified examples of fraud or abuse against the TRICARE program as including "[m]isrepresentations of . . . description of services rendered." 32 C.F.R. § 199.9(c).

28. To obtain TRICARE reimbursement for services from physicians or other authorized individual providers, as with Medicare, the providers must submit a claim form to TRICARE that lists the procedure code or narrative description for each procedure or service for each date of service. 32 C.F.R. § 199.7(b)(2)(ix)(B). TRICARE claim forms also must bear a signature of the participating provider certifying that the medical care billed for was rendered to the beneficiary. 32 C.F.R. § 199.7(c). This signature certifies that the specific medical care listed on the claim form was rendered to the specific beneficiary at the level indicated on the claim form. *Id*.

III. FACTUAL BACKGROUND

The P-Stim, ANSiStim, and Stivax Auricular Electro-Acupuncture Devices

29. Auricular electro-acupuncture devices are designed to deliver electrical current from a small portable unit, taped to the patient's skin, through acupuncture needles inserted into the skin of the patient's ear. The patient wears the device for a period of days while receiving the electrical current.

30. Auricular electro-acupuncture devices can be applied to a patient by someone with only minimal training.

31. Auricular electro-acupuncture devices can be applied to a patient in an office setting in a matter of minutes without anesthesia.

32. After the treatment, the patient can simply remove the auricular electro-acupuncture device themselves.

33. Medicare did not approve reimbursement for any form of acupuncture at any relevant time[2] and has never approved reimbursement for auricular electro-acupuncture.

The P-Stim Device

34. The P-Stim is an auricular electro-acupuncture device manufactured by an Austrian company, Biegler GmbH ("Biegler").

35. The FDA cleared the P-Stim in 2014 to be marketed in the United States pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("510(k) clearance").

36. The FDA's 510(k) clearance for the P-Stim states the following Indications for Use: "P-Stim is an electro-acupuncture device for the use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states." Exhibit B.

37. The FDA has never approved the P-Stim device for any indication.

38. The FDA only approves a device after a rigorous evaluation of safety and efficacy derived from scientific data and clinical trials. Further, the FDA approval process also involves testing to determine that a device meets appropriate quality standards. FDA approval is usually mandatory to market or sell products in the United States that might have a significant risk of injury or illness, but can also benefit health, such as prescription medications, over-the-counter medications, vaccines, and Class III medical devices.

39. By contrast, the FDA can grant a 510(k) clearance to a device if the manufacturer can demonstrate that their product is "substantially equivalent" to another similar legally

[2] Effective January 21, 2020, Medicare approved reimbursement for acupuncture for the limited indication of chronic lower back pain under section 1862(a)(1)(A) of the Act. Medicare beneficiaries with chronic lower back pain may receive coverage for up to 12 visits in 90 days, with an additional eight sessions covered for those beneficiaries demonstrating improvement, not to exceed 20 acupuncture treatments annually.

marketed device that already has FDA clearance or approval. Section 510(k) requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. This allows the FDA to determine whether the device is equivalent to a device already placed into one of three classification categories.

40. Biegler distributed the P-Stim device in the United States through multiple United States distributors.

41. One P-Stim distributor, DyAnsys, Inc. ("DyAnsys"), unsuccessfully applied to CMS in 2014 for a HCPCS code that would specifically describe the P-Stim.

42. CMS rejected DyAnsys's application for a HCPCS code that would specifically describe the P-Stim. CMS's 2014 decision stated that:

> A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish another code to identify a P-Stim, Electro-Acupuncture Stimulator device. Existing code S8930 "Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient" is available for assignment to insurers if they deem appropriate, to identify this service.

43. Medicare did not reimburse for S8930 at any relevant time, because it did not approve reimbursement for any form of electro-acupuncture at any relevant time.

The ANSiStim Device

44. DyAnsys manufactured and imported its own auricular electro-acupuncture device to compete with the P-Stim device.

45. DyAnsys originally also named its auricular electro-acupuncture device "P-Stim," but later re-named it "ANSiStim" (the "ANSiStim").

46. Like the P-Stim, the ANSiStim device can be applied to a patient in an office setting in a matter of minutes without anesthesia.

47. In 2015, the FDA provided 510(k) clearance for the ANSiStim device to be marketed in the United States. Exhibit C.

48. DyAnsys stated that the ANSiStim device was substantially equivalent to the P-Stim device when it applied to the FDA for the ANSiStim's 510(k) clearance. *Id*.

49. The FDA's 510(k) clearance for the ANSiStim device states the following Indications for Use: "ANSiStim is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states." *Id*.

50. The FDA has never approved the ANSiStim device for any indication.

The Stivax Device

51. The Stivax device is an auricular electro-acupuncture device manufactured by Biegler and promoted as a later generation of the P-Stim.

52. Like the P-Stim device and the ANSiStim device, the Stivax device can be applied to a patient in an office setting in a matter of minutes without anesthesia.

53. In 2016, the FDA provided 510(k) clearance for the Stivax device to be marketed in the United States. Exhibit D.

54. Biegler stated that the Stivax was substantially equivalent to the P-Stim when it applied to the FDA for Stivax's 510(k) clearance. *Id*.

55. The FDA's 510(k) clearance for the Stivax device states the following Indications for Use: "Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states."

56. The FDA has never approved the Stivax for any indication.

Warren's False Promotion of the P-Stim Device and the ANSiStim Device as Reimbursable by Medicare from 2014 to 2016

57. Warren promoted himself as an expert in medical billing and compliance at all relevant times and offered reimbursement and compliance consultation services through his companies ChiroMeetings and Titan Medical Compliance.

58. Warren advertised that he obtained certificates from the American Academy of Professional Coders in medical coding in 2007 and in medical compliance in 2011.

59. Access 2 Integration ("A2I") is a company that provided consulting services to chiropractic offices interested in becoming "integrated" practices at all relevant times.

60. In an "integrated" chiropractic practice, a licensed medical provider who has Medicare billing privileges, such as a nurse practitioner, provides services within a chiropractic office that a chiropractor is unqualified to perform and/or for which Medicare will not reimburse the chiropractor.

61. A2I promoted the P-Stim device and the ANSiStim device to its integrated practice clients, encouraging them to have a nurse practitioner apply them in the office to boost revenue.

62. Many of A2I's client's paid A2I to supply a nurse practitioner to work in their chiropractic office part-time to apply the P-Stim device and/or the ANSiStim device to patients.

63. Mark Kaiser ("Kaiser"), doing business as ProTech Medical, sold P-Stim and ANSiStim devices to A2I clients and to other medical providers.

64. Before medical providers, including integrated chiropractic practices, agreed to purchase P-Stim devices or ANSiStim devices, they frequently asked whether, and how much, Medicare would reimburse for the application of the devices and for the devices themselves so they could determine if the devices would be profitable.

65. Beginning as early as April of 2014, and continuing until 2018, A2I paid Warren $1,500 per month to advise its clients on how to set up integrated practices and how to generate revenue from Medicare reimbursements for procedures performed at the integrated practices.

66. Beginning at least as early as 2014, A2I relied on Warren to advise clients and prospective clients that Medicare would reimburse them for the P-Stim device and/or the ANSiStim device.

67. Beginning at least as early as 2014, Kaiser relied on Warren to advise customers and prospective customers that Medicare would reimburse them for the P-Stim device and/or the ANSiStim device.

68. Additionally, some medical practices paid Warren directly for reimbursement advice, including advice on seeking reimbursement from Medicare for the P-Stim device and the ANSiStim device.

69. Warren knew, beginning in approximately 2007, and at all relevant times thereafter, that Medicare did not allow reimbursement for acupuncture.

70. Warren nevertheless advised A2I clients, Kaiser's customers, and other medical providers that they could seek reimbursement from Medicare for (a) the procedure of applying the P-Stim device or the ANSiStim device, and (b) for the devices themselves.

71. For example, in or before 2015, Warren drafted a document entitled "Guidelines for P-Stim" that instructed medical providers on what CPT and HCPCS codes they should use to seek reimbursement from Medicare for the service of applying the P-Stim to a patient and for the P-Stim device itself. Exhibit E.

72. Warren provided the "Guidelines for P-Stim" document to Kaiser, knowing that Kaiser would provide the document, and/or the information contained in the document, to A2I for dissemination to medical providers that were A2I's clients.

73. Warren also knew that Kaiser would provide the "Guidelines for P-Stim" document, and/or the information contained in the document, to other medical providers in connection with Kaiser's sale and promotion of the P-Stim device and/or the ANSiStim device.

74. The coding advice that Warren memorialized in his "Guidelines for P-Stim" document is the same coding advice that Warren consistently provided directly, through Kaiser, and/or through A2I, to current and prospective P-Stim and ANSiStim customers in 2015 and 2016.

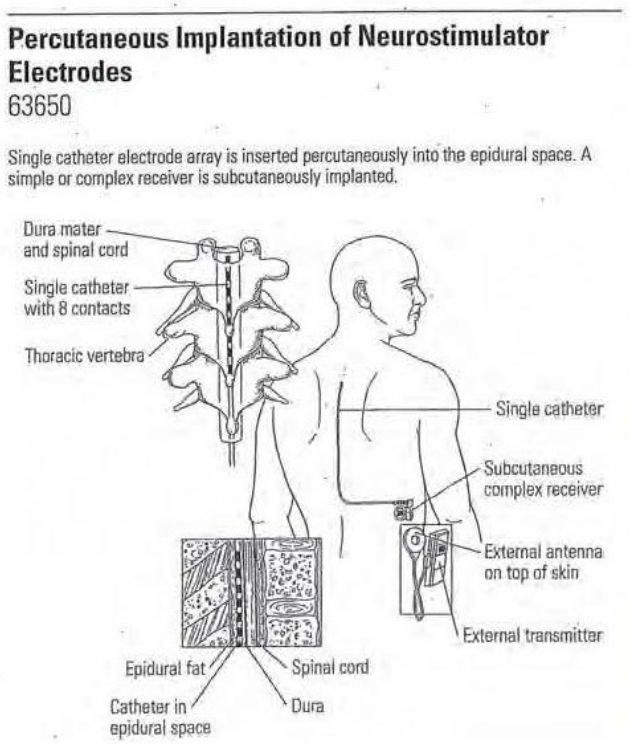
75. In 2015 and 2016, Warren consistently advised current and prospective P-Stim and ANSiStim customers to bill Medicare using CPT code 63650 to bill for the service of applying the device to a patient.

76. CPT code 63650 does not describe, and has never described, the service of applying an auricular electro-acupuncture device such as the P-Stim device or the ANSiStim device.

77. The AMA's 2015 CPT manual defines 63650 as a "percutaneous implantation of neurostimulator electrode array, epidural." The CPT manual further explains that 63650 and other related codes "describe the operative placement, revision, replacement, or removal of the spinal neurostimulator system components to provide spinal electrical stimulation."

78. The 2015 CPT manual includes a graphic depiction of the device that CPT code 63650 is intended to cover; the image depicts a catheter in the epidural space of the patient's

spine leading to an external unit near the patient's hip that does not resemble the P-Stim device or the ANSiStim device.



79. Warren knew at all relevant times that the procedure described by CPT code 63650 involved inserting a catheter into the epidural space around the patient's spine.

80. Warren knew at all relevant times that application of the P-Stim device and the ANSiStim device involved inserting acupuncture needles into a patient's ear and did not in any way involve the epidural space around the patient's spine.

81. Warren knew at all relevant times that CPT code 63650 did not describe the application of the P-Stim device or the ANSiStim device.

82. Warren knew when he disseminated his P-Stim coding guidelines that Medicare typically reimbursed $1,349 each time a provider requested reimbursement for 63650.

83. Warren advised A2I's clients and Kaiser's customers to bill CPT code 63650 five times for each patient. Accordingly, Warren knew that Medicare would potentially pay providers that followed his advice approximately $6,745 for each patient for CPT code 63650 alone.

84. Beginning in 2015, Warren also advised providers to bill Medicare using HCPCS code L8679 to seek reimbursement for the P-Stim device and the ANSiStim device.

85. HCPCS code L8679 does not describe, and has never described, an auricular electro-acupuncture device such as the P-Stim device or the ANSiStim device.

86. The AMA's 2015 HCPCS manual defines L8679 as an "implantable pulse generator, any type."

87. L8679 describes a class of complex devices that are surgically implanted into a patient by a highly trained physician in a surgical setting while the patient is under anesthesia.

88. Warren knew when he advised A2I clients and other providers to bill Medicare using L8679 for the P-Stim device and/or the ANSiStim device that his advice was not correct because Medicare did not reimburse for acupuncture devices.

89. Warren knew when he advised A2I clients and other providers to seek reimbursement from Medicare for the P-Stim device and the ANSiStim device using L8679 that Medicare typically reimbursed over $8,000 each time a provider billed L8679.

90. Warren advised A2I's clients and Kaiser's customers to bill L8679 twice during each course of treatment. Accordingly, Warren knew that Medicare would potentially pay providers that followed his advice over $16,000 in reimbursements for each patient for HCPCS code L8679 alone.

91. At least as early as January 2016, and likely earlier, Warren knew that CMS had rejected DyAnsys's 2014 application for a HCPCS code specifically describing the P-Stim and that CMS stated the only appropriate code to use in connection with the P-Stim device was S8930.

92. Warren knew that Medicare would not reimburse for S8930, because Medicare did not reimburse for acupuncture.

93. Warren continued to advise providers throughout 2015 and into 2016 that they should bill Medicare for the P-Stim device and the ANSiStim device using CPT code 63650 and HCPCS code L8679.

94. Warren drafted sample documents for Kaiser and A2I to distribute to actual and prospective P-Stim and/or ANSiStim customers to assist with their efforts to bill Medicare for the P-Stim and/or ANSiStim devices, including reimbursement guidance, treatment protocols, sample office notes, and a draft "Informed Consent" for patients to sign.

95. The "Informed Consent" document that Warren drafted and distributed for use by medical providers falsely stated that the P-Stim device and/or other auricular electro-acupuncture devices such as the ANSiStim device were "FDA approved" for the treatment of numerous chronic pain conditions. Exhibit F.

96. No auricular electro-acupuncture device has ever been approved by the FDA for any indication.

97. Warren's statement that the P-Stim device and/or other auricular electro-acupuncture devices were FDA approved was false and misleading.

98. Warren sent his sample "Informed Consent" document to A2I and Kaiser for distribution to A2I clients and other medical providers.

99. Warren's false and fraudulent advice to providers that Medicare would reimburse them thousands of dollars for applying the P-Stim device and/or the ANSiStim device and that P-Stim and other auricular electro-acupuncture devices were FDA approved, drove sales of the P-Stim device and the ANSiStim device and caused Medicare and other federal healthcare programs to pay millions of dollars in false claims.

Warren's False Promotion of Stivax as Reimbursable by Medicare from 2016 through 2018

100. In August 2016, Novitas Solutions, Inc. ("Novitas"), a MAC, issued a Local Coverage Article stating that Medicare did not cover peripheral nerve stimulation or electro-acupuncture performed with electro-acupuncture devices. Exhibit G (the "Novitas Coverage Article").

101. Local Coverage Articles are a type of educational document that MACs publish, often containing coding or other guidelines that are related to a Local Coverage Determination or a National Coverage Determination.

102. Novitas, having detected a substantial amount of inappropriate billing for auricular electro-acupuncture devices, issued the Novitas Coverage Article to make explicit what the average, honest provider already knew: Medicare does not reimburse for the device.

103. The Novitas Coverage Article also stated, among other things, that "[w]hile the information in this article is directed to Neurostim system/NSS, P-Stim, ANSiStim, E-Pulse, and NSS-Bridge, other current or future devices when used for the procedure of auricular peripheral nerve stimulation or electro-acupuncture, would also be denied as a non-covered service."

104. The Novitas Coverage Article applied to the Stivax device, because it was an electro-acupuncture device, even though the article did not specifically name the Stivax device.

105. Warren received the Novitas Coverage Article by email on August 16, 2016 and reviewed it.

106. James Carpenter ("Carpenter") owned and operated Eagle Advancement Institute in and prior to 2016, through which he imported P-Stim devices from Biegler for distribution in the United States.

107. Carpenter and Kaiser both learned of the Novitas Coverage Article in August of 2016 and decided the direct reference to P-Stim could hinder P-Stim sales.

108. In or about the fall of 2016, Carpenter founded Solace Advancement Institute ("Solace") to import Stivax devices from Biegler into the United States.

109. Kaiser stopped distributing the P-Stim device through ProTech in or about the fall of 2016 and founded Doc Solutions, LLC to distribute the Stivax device.

110. In or about the fall of 2016, Solace entered into an agreement with Kaiser, doing business as Doc Solutions (hereafter collectively "Kaiser"), pursuant to which Solace would sell the Stivax devices that it imported to Kaiser and Kaiser would market and sell the Stivax devices to medical providers throughout the United States.

111. Carpenter and Kaiser understood that convincing customers they could seek reimbursement from Medicare for the Stivax device was critical for sales.

112. In or about the fall of 2016, Solace entered into an agreement with Warren whereby it agreed to pay Warren $1,000 per month to advise prospective and current Stivax customers on how to seek reimbursement from Medicare for the Stivax device.

113. Therefore, beginning in the fall of 2016, Warren earned $2,500 per month ($30,000 per year) collectively from Solace and A2I to provide coding and compliance advice to current and prospective Stivax customers.

114. Beginning in or about the fall of 2016, and continuing through 2018, Warren played a vital role in the sales model that Kaiser and Carpenter devised to sell the Stivax device.

115. Carpenter, Kaiser, and Warren understood that Kaiser would identify sales leads, frequently integrated chiropractic practices, and would introduce Warren as an expert in seeking reimbursement for the Stivax device.

116. Warren's role was to advise current and prospective Stivax customers that they could bill Medicare for applying the Stivax to patients and for the Stivax device itself and could expect thousands of dollars in Medicare reimbursements.

117. When current or prospective Stivax customers expressed reservations about billing Medicare for the Stivax, Warren's role was to reassure them that they could do so.

118. Warren drafted and disseminated through Kaiser several sets of written coding advice from 2016 through the end of 2018 advising Stivax customers and prospective customers that they could bill Medicare for the service of applying the Stivax and for the Stivax itself.

119. Between 2016 and 2018, Warren recommended that providers use a variety of CPT codes to bill Medicare for the procedure of applying the Stivax, including: 64553, 64555, 63663, 95970, 95971, and 95972.

120. Each of these CPT codes described procedures performed by highly trained physicians in connection with the surgical implantation and/or programing of sophisticated stimulator devices.

121. None of these CPT codes describe or refer to the procedure of applying the Stivax device or any other auricular electro-acupuncture device.

122. Between 2016 and 2018, Warren recommended that providers use HCPCS code L8679 to bill Medicare for the Stivax device itself.

123. Warren advised current and prospective Stivax customers that they could expect Medicare to pay them a reimbursement of approximately $8,000 each time they billed L8679.

124. L8679 did not describe the Stivax device or any other auricular electro-acupuncture device.

125. Warren communicated his advice directly to both current and prospective Stivax customers in late 2016, 2017, and 2018 at Kaiser's direction and on his own when contacted by providers.

126. Warren also drafted, and Kaiser disseminated, multiple written protocols in late 2016, 2017, and 2018 directing providers on when and how to bill Medicare for applying the Stivax device and for the Stivax device itself.

127. For example, Warren drafted a document entitled "Coding for the Stivax Stimulator" that Kaiser distributed to his Stivax customers by email on December 13, 2017. Warren's "Coding for the Stivax Stimulator" document fraudulently advised providers to bill Medicare for the Stivax using HCPCS code L8679 and CPT codes 63663 and 95970 and for associated office visits using CPT code 99213. Exhibit H.

128. Warren drafted a model Informed Consent document for the Stivax that Kaiser and/or A2I distributed to Stivax customers. Warren's informed consent document falsely stated that the "Stivax stimulator is FDA approved for the treatment of" a variety of pain indications. Exhibit I.

129. The Stivax device is not FDA approved for any indication.

Warren Knew at All Relevant Times that Medicare Would not Approve Reimbursement for the Stivax Device

130. Warren knew by late 2016 that the FDA 510(k) clearance for the Stivax stated that it was an electro-acupuncture device, just like the P-Stim device and the ANSiStim device.

131. Accordingly, Warren knew that the Novitas Coverage Article applied to the Stivax device even though the article did not specifically mention the Stivax device.

132. Warren repeatedly received additional information further confirming that Medicare would not reimburse for auricular electro-acupuncture devices.

133. On or about October 19, 2016, Warren received the results of an audit performed by a coding consultant hired by a chiropractor who had followed Warren's advice to bill L8679 for P-Stim. The consultant stated, among other things that "L8679 is for implantable stimulator, but P-Stim does not meet the Medicare definition of implantable. Discontinue utilizing L8679… It is my expectation that the devices will not be covered as Medicare has stated that auricular point stimulation devices are not covered by Medicare."

134. On or about October 25, 2016, Warren received an email from A2I attaching an audit that SafeGuard Services, a Medicare integrity contractor, performed at an integrated chiropractic office that had billed HCPCS code L8679 for P-Stim devices. The audit results showed that acupuncture was not covered by Medicare and that providers should not bill L8679 for auricular electro-acupuncture devices.

135. On or about December 12, 2016, Warren received a Local Coverage Determination issued in 2015 by Noridian Healthcare Solutions, a MAC, that stated: "The P-Stim is a miniaturized electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture. It provides auriculo-point stimulation treatment over several days. This item is not reimbursable by Medicare."

136. Local Coverage Determinations are decisions made by a MAC whether to cover a particular item or service in a MAC's jurisdiction (region) in accordance with section 1862(a)(1)(A) of the Social Security Act. The MAC's decision is based on whether the service or item is considered reasonable and necessary.

137. On or about December 19, 2016, a chiropractor and Stivax customer forwarded to Warren a coverage advisory from Wisconsin Physician Services, a MAC, stating that electro-acupuncture "is not a Medicare covered service."

138. On or about December 27, 2016, a different chiropractor forwarded to Warren a coverage advisory from Physicians Business Solutions, a MAC, stating that 64555 and L8679 should not be used to seek reimbursement for auricular electro-acupuncture devices. The notice included two articles issued by the AMA supporting its conclusion.

139. On or about August 7, 2017, Warren read another coverage advisory from Wisconsin Physician Services, a MAC, stating among other things that "[P-Stim] is a miniature device designed to administer auricular point stimulation treatment over several days. P-Stim is not the same service as the implantation of electrical nerve stimulators…."

140. Warren knew that advisories stating that Medicare would not pay for the P-Stim device, or any other electro-acupuncture device, meant that Medicare would not approve reimbursement for the Stivax device.

Warren's Fraudulent Reimbursement Advice Caused Medicare to Pay Millions of Dollars in False Claims

141. Warren's false and fraudulent advice to providers that Medicare would reimburse them thousands of dollars for applying the P-Stim device, the ANSiStim device, and the Stivax device and his false representations to providers that these devices were FDA approved, drove

sales of the devices, and caused Medicare and other federal healthcare programs to pay millions of dollars in false claims.

142. Warren's fraudulent advice that providers should bill Medicare for auricular electro-acupuncture devices by submitting HCPCS code L8679 caused Kaiser's customers to submit over 3,000 false claims to Medicare for the P-Stim, ANSiStim, and/or Stivax devices between 2015 and 2019, for which Medicare paid over $20 million.

143. Warren's fraudulent advice that providers should bill Medicare for applying auricular electro-acupuncture devices by submitting CPT codes 64553 and/or 64555 caused Kaiser's customers to submit at least 350 false claims to Medicare for applying the P-Stim, ANSiStim, and/or Stivax devices between 2016 and 2019, for which Medicare paid over $50,000. *See* Exhibit A.

Warren's Fraudulent Reimbursement Advice Caused TRICARE to Pay Nearly Two Hundred Thousand Dollars in False Claims

144. Warren's fraudulent advice that providers should bill TRICARE for applying auricular electro-acupuncture devices by submitting, among other codes, HCPCS code L8679 and CPT codes 63650, 64553, 63663, and 64555, caused Kaiser's customers to submit at least 314 false claims to TRICARE for applying the P-Stim, ANSiStim, and/or Stivax, for which TRICARE paid over $177,000 between 2014 and the present.

Representative Examples of Providers Who Submitted False Claims Caused by Warren's Fraudulent Reimbursement Advice

145. Warren falsely and fraudulently advised many medical providers to seek reimbursement from Medicare for the P-Stim device, ANSiStim device, and/or the Stivax device which caused those providers to submit thousands of false claims to Medicare. These providers

included, but were not limited to, Neurosurgical Care, LLC, Campbell Medical Clinic, Align Health & Holistic Medical Center, and A.C.W, Inc.

Neurosurgical Care, LLC

146. Neurosurgical Care, LLC is a neurosurgical medical practice based in Royersford, Pennsylvania which is within the Eastern District of Pennsylvania.

147. Sagi Kuznits, M.D. is a board-certified neurosurgeon licensed to practice medicine in Pennsylvania.

148. Neurosurgical Care, LLC is Dr. Kuznits's medical practice.

149. Dr. Kuznits provides medical services at multiple locations within the Eastern District of Pennsylvania.

150. Kaiser, operating as Doc Solutions, marketed the Stivax device to Dr. Kuznits within the Eastern District of Pennsylvania in 2017.

151. When Kaiser, operating as Doc Solutions, marketed the Stivax device to Dr. Kuznits within the Eastern District of Pennsylvania in 2017, he communicated Warren's false and fraudulent instructions to use L8679 to bill Medicare for the Stivax device to Dr. Kuznits.

152. Kaiser met with Dr. Kuznits at the offices of Neurosurgical Care, LLC in early 2017.

153. When Kaiser met with Dr. Kuznits in early 2017, Kaiser provided Dr. Kuznits with Warren's instructions to bill Medicare for the Stivax device using L8679 that Warren drafted for Kaiser to use for marketing the Stivax.

154. On March 14, 2017, when Dr. Kuznits asked Kaiser by email to confirm that L8679 was an appropriate code to use to bill Medicare for the Stivax device, Kaiser responded by providing a link to Warren's LinkedIn profile and citing Warren as "our compliance officer."

155. On March 15, 2017, Kaiser sent an email to Warren and Dr. Kuznits introducing them to one another and stating to Warren that Dr. Kuznits "would like to speak to you briefly regarding compliance matters of the Stivax device."

156. Warren provided coding advice concerning the Stivax device directly to Dr. Kuznits.

157. In 2017, Kaiser repeatedly conveyed Warren's false and fraudulent advice to use L8679 to bill Medicare for the Stivax device to Dr. Kuznits.

158. On December 13, 2017, Kaiser disseminated by email a new set of Stivax coding instructions that Warren prepared to Stivax customers, including Dr. Kuznits. This set of instructions again recommended that providers use L8679 to bill Medicare for the Stivax device.

159. Based on the false and fraudulent billing instructions that Warren provided directly, and/or through Kaiser, to Dr. Kuznits, Neurosurgical Care, LLC submitted over 50 false claims to Medicare using L8679 in 2017 and 2018 for which Medicare paid nearly $400,000.

Campbell Medical Clinic

160. Johnson Medical Group PLLC, d/b/a Campbell Medical Clinic ("Campbell") is an integrated chiropractic practice located in Houston, Texas.

161. A chiropractor, Suhyun An, managed and provided clinical chiropractic services at Campbell.

162. Dr. An contacted Kaiser by email on December 16, 2015 indicating her interest in offering the P-Stim device to Campbell patients.

163. Dr. An expressed to Kaiser her concerns about whether Campbell could legally bill commercial insurance carriers and federal health care programs for the P-Stim device.

164. Kaiser informed Dr. An by email on December 16, 2015 that Medicare and commercial payers reimburse for P-Stim treatments and that "[a]ll of my coding recommendations are backed by Dr. Tim Warren DC…."

165. Kaiser informed Dr. An by email on December 16, 2015 that she could expect to receive between $3,000 and $6,000 in reimbursements for P-Stim treatments "per the coding recommended by Dr. Warren."

166. Dr. An repeatedly informed Kaiser by email in late December of 2015 that she was reluctant to start using the P-Stim device at Campbell because she was concerned, based on her own research, that it was not legal to bill to Medicare.

167. Kaiser stated to Dr. An that Warren "is the one who is working with me on all of the coding and getting docs more comfortable getting going with this therapy along with aiding them in proper documentation for both commercial and federal payers."

168. Dr. An agreed to speak to Warren regarding her concerns.

169. Dr. An informed Kaiser, "If I can get a confident assurance from Dr. Warren, with proven [track] record that Pstim has survived medicare [sic] audits, I am ready to start."

170. Dr. An sent an email to Warren on December 27, 2015 stating: "I am interested in bringing P-Stim to my office but am reading conflicting information on legality of billing it to different payor [sic], especially to Medicare. Mark [Kaiser] says you have it figured out how to make it compliant."

171. In December of 2015 and January of 2016, Dr. An repeatedly expressed her concerns to Warren and Kaiser about the legality of billing Medicare for the P-Stim.

172. In December of 2015 and January of 2016, Warren spoke to Dr. An on the telephone and corresponded with her by email to convince her that Campbell could bill Medicare for the P-Stim device.

173. By email on January 11, 2016, Dr. An asked Warren about CMS's decision to reject DyAnsys's 2014 application for a HCPCS code that described the P-Stim device.

174. The same day, Warren responded to Dr. An by minimizing the significance of the DyAnsys HCPCS application and falsely stating to Dr. An that CMS "ha[s] not acted on that item yet." Warren went on to advise Dr. An that he was "still recommending the coding as discussed last week."

175. In January of 2016, Warren falsely advised Dr. An directly and through Kaiser that Campbell could bill Medicare for the procedure of applying the P-Stim device using CPT code 63650 and for the P-Stim device itself using HCPCS code L8679.

176. Nurse practitioners affiliated with Campbell began affixing the P-Stim to patients in January of 2016.

177. Based on Warren's advice, Campbell billed Medicare using L8679 for the P-Stim devices it applied to patients using HCPCS code L8679.

178. On May 11, 2016, Warren acknowledged to Dr. An in an email that his coding advice "is not 100% complaint."

179. Warren nevertheless continued to recommend to Dr. An that Campbell continue to bill Medicare for the P-Stim device.

180. Later in 2016, Warren falsely advised Dr. An directly and/or through Kaiser that Campbell could also bill Medicare for the procedure of applying the P-Stim device using CPT codes 64553 and 64555.

181. In or around September of 2016, Warren and Kaiser encouraged Dr. An and Campbell to switch from using the P-Stim device to using the Stivax device.

182. In or around September and October of 2016, Warren falsely advised Dr. An that Campbell could bill Medicare for the procedure of applying the Stivax using CPT codes 64553 and 64555 and for the Stivax device using HCPCS code L8679.

183. In November of 2016, Warren emailed Dr. An written coding recommendations for Stivax that recommended, among other things, that providers use L8679 to bill Medicare for the Stivax device.

184. In November of 2016, Warren emailed Dr. An an Informed Consent document for Stivax patients to sign that falsely stated that the Stivax device was FDA approved for numerous chronic pain indications.

185. Nurse practitioners affiliated with Campbell began affixing the Stivax device to patients in or around the fall of 2016.

186. In late 2017, Warren drafted a new document of revised coding advice for providers using the Stivax device. Warren's new Stivax coding advice falsely advised providers that they could bill Medicare for the procedure of affixing the Stivax to a patient using 63663 and for the Stivax device itself using L8679.

187. On December 13, 2017, Kaiser distributed Warren's new coding advice by email to many Stivax customers including Dr. An.

188. Relying on Warren's false advice that Campbell could bill Medicare for the procedure of applying the P-Stim device and the Stivax device to a patient, Campbell submitted over one hundred false claims to Medicare using CPT 64555 in 2016 for which Medicare paid Campbell over $15,000.

189. Relying on Warren's false advice that Campbell could use HCPCS code L8679 to bill Medicare for the P-Stim device and the Stivax device, Campbell submitted over 600 false claims to Medicare using HCPCS code L8679 between 2016 and 2018 for which Medicare paid Campbell over $3.8 million.

190. Accordingly, Warren caused Campbell to submit over 700 false claims to Medicare between 2016 and 2018 causing Medicare to pay Campbell over $3.8 million.

Align Health & Holistic Medical Center

191. Align Health and Holistic Medical Center, LLC ("Align") is an integrated chiropractic practice located in Maryville, Tennessee.

192. Align was a client of A2I and learned about the P-Stim device in 2016 when A2I recommended that Align use a nurse practitioner provided by A2I to apply P-Stim and/or Stivax devices to Align patients.

193. Pursuant to its agreement with Align, A2I provided a nurse practitioner to Align to apply the P-Stim and/or Stivax devices to Align patients.

194. On September 2, 2016, Oxenrider sent the nurse practitioner the written coding guidelines that Warren prepared for the P-Stim device and/or the Stivax device.

195. Warren's coding guidelines recommended that providers use CPT code 63650 to seek reimbursement for the procedure of applying the P-Stim and/or Stivax to a patient and HCPCS code L8679 for the device itself.

196. Align began ordering P-Stim devices through Kaiser in September of 2016 and, in reliance on Warren's reimbursement advice, submitted claims to Medicare for the P-Stim device using HCPCS code L8679.

197. Kaiser convinced Align to transition from the P-Stim device to the Stivax device in November of 2016.

198. Kaiser informed Align on November 3, 2016 that a "1 hour paid call with Dr. Warren to go over coding / billing / compliance" would be included with Align's first order of Stivax devices.

199. On November 21, 2106, Warren emailed documents directly to Align that he prepared to assist them with using and billing for the Stivax.

200. Among the documents Warren provided to Align was an Informed Consent document that Warren drafted for use with Align patients. The Informed Consent document falsely stated that the Stivax device was FDA approved for numerous chronic pain indications.

201. Warren provided Stivax coding and reimbursement advice to Align in 2016, 2017, and 2018.

202. On April 9, 2018, Warren entered a contract with Align to provide more extensive coding and reimbursement advice among other services.

203. Throughout 2016, 2017, and 2018, Warren consistently, directly and/or through Kaiser and/or Oxenrider, provided false advice to Align that Medicare would reimburse for the procedure of applying the P-Stim device and/or the Stivax device.

204. Between 2016 and 2018, Warren advised Align to use several different CPT codes to seek reimbursement from Medicare for the procedure of applying the P-Stim device and/or the Stivax device, including 63663, 64553, and 64555.

205. Between 2016 and 2018, Warren consistently advised Align to use HCPCS code L8679 to seek reimbursement from Medicare for the P-Stim device and/or the Stivax device.

206. Relying on Warren's false advice that Align could bill Medicare for the procedure of applying the P-Stim device and the Stivax device to a patient, Align and/or Nurse Practitioner C.B. submitted over two hundred false claims to Medicare using CPT codes 63663, 64553, and 64555 between 2016 and 2019 for which Medicare paid Align over $25,000.

207. Relying on Warren's false advice that Align could use HCPCS code L8679 to bill Medicare for the P-Stim and Stivax devices, Align and/or Nurse Practitioner C.B. submitted nearly 250 false claims to Medicare using HCPCS code L8679 between 2016 and 2019 for which Medicare paid over $1.1 million.

208. Accordingly, Warren caused Align to submit over 400 false claims to Medicare between 2016 and 2019 causing Medicare to pay Align over $1.1 million.

A.C.W., Inc.

209. A.C.W., Inc. ("ACW") was an integrated chiropractic practice located in Chattanooga, Tennessee.

210. In or about November of 2015, another medical provider introduced Warren to ACW as a reimbursement and compliance expert.

211. In or about January of 2016, ACW contacted Warren as it considered whether to start offering auricular electro-acupuncture devices to its patients.

212. Warren introduced ACW to Kaiser, who was selling the ANSiStim device at the time.

213. Kaiser referred ACW to Warren for questions regarding how ACW could seek reimbursement for the ANSiStim application and device from commercial payors as well as Medicare.

214. Warren informed ACW that he had expertise in medical compliance and reimbursement.

215. Warren informed ACW, orally and by providing documents to ACW that he drafted, that it was appropriate to use CPT code 63650 and HCPCS code L8679 to bill Medicare for the ANSiStim device.

216. Warren provided ACW an Informed Consent document that falsely stated that the "neurostimulator" that ACW would use, *e.g.*, the ANSiStim, was "FDA approved" for five pain related indications.

217. Warren provided reimbursement guidelines that he drafted to ACW informing ACW that they could expect Medicare to reimburse over $1,300 each time they billed CPT code 63650 and $8,000 each time they billed HCPCS code L8679.

218. On May 4, 2016, Warren emailed to ACW representative C.C. a document he characterized as "sample note requirements for Medicare" to guide ACW on how to draft its medical records to ensure reimbursement from Medicare for the ANSiStim.

219. ACW started offering the ANSiStim to its patients and submitting claims for reimbursement to both commercial insurance carriers and Medicare based on, and in accordance with, Warren's advice and guidance.

220. Based on Warren's false advice that ACW could bill Medicare for the Stivax device, ACW submitted over 90 claims to Medicare for HCPCS code L8679 between June of 2016 and June of 2017, for which Medicare paid ACW over $550,000.

221. Warren's false reimbursement advice and false promotion of the ANSiStim as FDA approved caused ACW to submit false claims to Medicare for L8679.

222. Accordingly, Warren caused ACW to submit over 90 false claims to Medicare between 2016 and 2019 causing Medicare to pay ACW over $550,000.

COUNT I

(FCA: Presentment of False Claims (31 U.S.C. § 3729(a)(1)(A))

223. The United States incorporates by reference the paragraphs above as if fully set forth in this Paragraph.

224. As detailed above, Defendants knowingly caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims for reimbursement by the Medicare Program that were false and fraudulent because they were for services for which the Medicare Program does not reimburse.

225. Defendants caused the Medicare Program to pay at least $20 million for over 3,000 false claims related to the Stivax device alone, and probably more.

226. As detailed above, the Medicare Program would not otherwise have paid for these false and fraudulent claims.

227. Defendants caused these claims to be presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

228. Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than $20 million in single damages, trebled, as well as civil penalties of a minimum penalty of $11,665 to a maximum penalty of $23,331 for each claim submitted to the Medicare Program and TRICARE.

COUNT II

(FCA: Making or Using False Statements Material to a False Claim

(31 U.S.C.§ 3729(a)(1)(B))

229. The United States incorporates by reference the paragraphs above as if fully set forth in this Paragraph.

230. As detailed above, Defendants knowingly caused to be made or used, false statements, which included false certifications and representations on forms CMS 1500 and/or its electronic equivalent, known as the 837P form, to obtain approval for and payment by the United States for false or fraudulent claims as detailed above.

231. Defendants' false representations were made for the purpose of causing that the Medicare Program paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

232. The false certifications and representations caused to be made by Defendants were material to the payment of the false claims by the United States.

233. The false statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

234. Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than $20 million in single damages, trebled, as well as a minimum civil penalty of $11,665 to a maximum penalty of $23,331 for each claim submitted to the Medicare Program and TRICARE.

Count III

(Payment by Mistake)

235. The United States incorporates by reference the paragraphs above as if fully set forth in this Paragraph.

236. The United States paid providers who followed Defendants' advice, either directly or indirectly, for services that were (i) not medically necessary; and/or (ii) did not otherwise satisfy the requirements of the Medicare Program and TRICARE, without knowledge of material facts, and under the mistaken belief that the providers who followed Defendants' advice were entitled to receive payment for such claims.

237. The mistaken belief of the United States was material to their decision to pay providers who followed Defendants' advice for such claims.

238. The United States reasonably relied on the submission of claims made by providers who followed Defendants' advice that the United States believed were accurate, complete, and truthful, in accordance with the express requirements of the Medicare Program and TRICARE.

239. The United States has been damaged because of this mistaken payment, and Defendants are thus liable to account and pay to the United States such amounts, which are to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, as follows:

I. On the First and Second Counts under the FCA for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such relief as may be just and proper.

II. On the Third Count for payment by mistake, for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial.

THE UNITED STATES OF AMERICA

DATED: 10/12/21

BY:

JENNIFER ARBITTIER WILLIAMS
Acting United States Attorney

GREGORY DAVID
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